

allocation shall be reduced from its allocated amount under Pub. L. 103-332 by the same percentage as total program allocations for the fiscal year fall below the total program allocations under Pub. L. 103-332.

(d) All data sources used in the development of the formula are publicly available. The relevant data is available from the Bureau of the Census, the Department of Energy's Energy Information Administration and the National Oceanic and Atmospheric Administration.

(e) Should updates to the data used in the formula become available in any fiscal year, these changes would be implemented in the formula in the following program year.

(f) DOE may reduce the program allocation for a State by the amount DOE determines cannot be reasonably expended by a grantee to weatherize dwelling units during the budget period for which financial assistance is to be awarded. In reaching this determination, DOE will consider the amount of unexpended financial assistance currently available to a grantee under this part and the number of dwelling units which remains to be weatherized with the unexpended financial assistance.

(g) DOE may increase the program allocation of a State by the amount DOE determines the grantee can expend to weatherize additional dwelling units during the budget period for which financial assistance is to be awarded.

(h) The Support Office Director shall notify each State of the program allocation for which that State is eligible to apply.

4. Section 440.12 is amended by revising paragraph (b)(4) to read as follows:

§ 440.12 State applications.

* * * * *

(b) * * *

(4) The total number of dwelling units proposed to be weatherized with grant funds during the budget period for which assistance is to be awarded—

(i) With financial assistance previously obligated under this part, and

(ii) With the program allocation to the State;

* * * * *

5. Section 440.14 is amended by revising paragraph (b)(9)(vi) to read as follows:

§ 440.14 State plans.

* * * * *

(b) * * *

(9) * * *

(vi) The amount of weatherization grant funds allocated to the State under this part;

* * * * *

[FR Doc. 95-13437 Filed 6-2-95; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Hoffmann-La Roche, Inc. The supplemental NADA provides for the use of 20 percent of lasalocid Type A medicated article in making Type C medicated feed used for chukar partridges as a coccidiostat.

EFFECTIVE DATE: June 5, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110, is the sponsor of NADA 96-298, which currently provides for the use of a Type A medicated article HFV238 containing 20 percent (90.7 grams per pound (g/lb)) of lasalocid sodium activity in making 68- to 113-g per ton (g/t) Type C medicated feed for broiler or fryer chickens. The firm has filed a supplemental NADA that expands the use of the article to make a 113-g/t Type C medicated feed for chukar partridges for the prevention of coccidiosis caused by *Eimeria legionensis*. Approval is based in part on data and information in Public Master File (PMF) 5429 established under the Interregional Research Project No. 4 (IR-4), Northeastern Region, New York State College of Veterinary Medicine, Cornell University, Ithaca, NY 14853-6401.

The supplemental NADA is approved as of April 19, 1995, and the regulations are amended in § 558.311 (21 CFR 558.311) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Additionally, in a final rule published in the **Federal Register** of August 6, 1990 (55 FR 31827), that amended the regulations in § 558.311(e)(1), the agency failed to also revise § 558.311(b)(6) to remove reference to entry (xiii) in the table in paragraph (e)(1). This document corrects that error.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.311 is amended in paragraph (b)(6) by removing "(e)(1)(xiii)," by adding new paragraph (b)(7), and in the table in paragraph (e)(1) by adding new entry "(xiii)" to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *

(7) 20 percent activity to No. 000004 for use in chukar partridges as in paragraph (e)(1)(xiii) of this section.

* * * * *

(e)(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xiii) 113 (0.0125 pct).	Chukar partridges; for prevention of coccidiosis caused by <i>Eimeria leionensis</i> .	Feed continuously as sole ration up to 8 weeks of age.	000004

* * * * *
 Dated: May 24, 1995.

Stephen F. Sundlof,
 Director, Center for Veterinary Medicine.
 [FR Doc. 95-13636 Filed 6-2-95; 8:45 am]
 BILLING CODE 4160-01-F

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Hoffmann-La Roche, Inc. The supplemental NADA provides for the use of a 20-percent lasalocid Type A medicated article in making Type C medicated feed used for growing turkeys as a coccidiostat.

EFFECTIVE DATE: June 5, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110, is the sponsor of NADA 96-298, which currently provides for the use of a Type A medicated article containing 20 percent (90.7 grams per pound (g/lb)) of lasalocid sodium activity in making a 68- to 113-g-per-ton (g/t) Type C medicated feed for broiler or fryer

chickens and chukar partridges. The firm has filed a supplemental NADA that expands the use of the article to making a 68- to 113-g/t Type C medicated feed for growing turkeys for the prevention of coccidiosis caused by *Eimeria meleagritidis*, *E. gallopavonis*, and *E. adenoeides*.

The supplemental NADA is approved as of April 28, 1995, and the regulations are amended in 21 CFR 558.311 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning April 28, 1995, because the supplemental application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the described use of lasalocid sodium in growing turkeys for which the supplemental application was approved.

The agency has carefully considered the potential environmental effects of

this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.311 is amended in paragraph (b) by revising paragraph (b)(7) and in the table in paragraph (e)(1) by adding new entry "(xiv)" to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *

(7) 20 percent activity to No. 000004 for use in chukar partridges as in paragraph (e)(1)(xiii) and for use in turkeys as in paragraph (e)(1)(xiv) of this section.

* * * * *

(e)(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xiv) 68 (0.0075 pct) to 113 (0.0125 pct).	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagritidis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> .	Feed continuously as sole ration.	000004